

**IN THE UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF TEXAS**

**GENSETIX, INC.,**

**Plaintiff,**

**and**

**THE BOARD OF REGENTS OF THE  
UNIVERSITY OF TEXAS SYSTEM,**

**Involuntary Plaintiff,**

**v.**

**BAYLOR COLLEGE OF MEDICINE,  
DIAKONOS RESEARCH, LTD.,  
and WILLIAM K. DECKER,**

**Defendants.**

Civil Action No. 4:17-cv-01025

**JURY TRIAL DEMANDED**

**GENSETIX, INC.'S FIRST AMENDED COMPLAINT**

Plaintiff Gensetix, Inc., along with Involuntary Plaintiff The Board of Regents of the University of Texas System, in support of the complaint against Defendants Baylor College of Medicine, Diakonos Research, Ltd., and William K. Decker (collectively “Defendants”), herein alleges as follows:

**NATURE OF THE ACTION**

1. While working for The University of Texas MD Anderson Cancer Center, Professor William Decker invented methods of modifying a patient’s immune system to kill cancer cells. He patented those methods in United States Patent Nos. 8,728,806 (“the ’806 patent”) (Exhibit A) and 9,333,248 (“the ’248 patent”) (Exhibit B) (together, the “Patents-in-Suit”). And then, as is common in academia, he assigned those patents to his employer, UT. No one disputes that his work, if ever commercialized, will undoubtedly help cancer patients.

2. But, because of Dr. Decker’s own subsequent actions and those of the other defendants, Gensetix—the exclusive licensee to the Patents-in-Suit—may never be able to bring Decker’s scientific breakthroughs to the marketplace. Instead of supporting Gensetix’s efforts and respecting his assignment to UT of the right to control who sells and uses his prior work, Decker, now a professor at Baylor College of Medicine, has used and continues to use the patented methods in pursuit of his next invention, and ultimately, a commercial product. Along the way, he has violated a non-disclosure agreement, purposely torpedoed Gensetix’s nearly-culminated third-party financing, and generated and wrongly conveyed additional intellectual property that is rightfully Gensetix’s to BCM, and ultimately, Diakonos.

3. Accordingly, Gensetix—a company that shares Dr. Decker’s laudable goal of curing cancer—brings this civil action for patent infringement and related misconduct so that it can transform Decker’s innovations into real patient benefits.

### **THE PARTIES**

4. Plaintiff Gensetix, Inc. (“Gensetix”) is a Delaware corporation, and its principal place of business is 3119 Mountain Oak Court, Houston, Texas 77068.

5. Involuntary Plaintiff, The Board of Regents of The University of Texas System (“UT”), is an agency of the State of Texas, located at 201 West 7th Street, Austin, Texas 78701.

6. UT owns the Patents-in-Suit and licenses them to Gensetix. Gensetix’s license is exclusive, and upon information and belief, Gensetix holds all commercial rights in the Patents-in-Suit.

7. Before filing this action, Gensetix requested that UT join the present suit as a co-plaintiff, but UT declined that request and refused to voluntarily join as a co-plaintiff.

8. Insofar as UT is deemed a necessary and indispensable party to the assertion of Counts 1 and 2 for patent infringement and injunctive relief, and is not subject to service of

process, Gensetix has joined UT as an Involuntary Plaintiff in this action pursuant to Rule 19(a) of the Federal Rules of Civil Procedure.

9. On information and belief, defendant Baylor College of Medicine (“BCM”) is a private university institution, located at One Baylor Plaza, Houston, Texas 77030.

10. On information and belief, defendant Diakonos Research Ltd. (“Diakonos”) is a limited liability corporation in Texas, and names Dan C. Faust as the registered agent.

11. On information and belief, defendant William K. Decker (“Decker”) is an individual who resides in Houston, Texas, and is employed at Baylor College of Medicine, One Baylor Plaza, Houston, Texas 77030.

12. Decker was formerly affiliated with UT, but is now affiliated with BCM.

### **JURISDICTION AND VENUE**

13. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

14. The complaint presents federal question jurisdiction for patent infringement, under Title 35, U.S.C. § 101, *et seq.*, and supplemental jurisdiction for other related causes of action which arise from substantially the same transactions and occurrences set forth below.

15. This Court has personal jurisdiction over BCM, Diakonos, and Decker because they are residents in this State. Defendants have committed and will commit acts of patent infringement in this State.

16. Venue is proper in this judicial district under 28 U.S.C. §§ 191(b) and (c) and § 1400(b) and because BCM, Diakonos, and Decker are residents in this District. Defendants have committed and will commit acts of patent infringement in this District.

**FACTS AS TO ALL COUNTS**

**The Patents-in-Suit**

17. The '806 patent, entitled "Methods and composition related to Th-1 dendritic cells," was duly and legally issued by the United States Patent and Trademark Office ("PTO") on May 20, 2014.

18. The '248 patent, entitled "Methods and composition related to Th-1 dendritic cells," was duly and legally issued by the PTO on May 10, 2016.

19. Decker is a named inventor on the Patents-in-Suit.

20. The Patents-in-Suit claim a priority date of December 6, 2008. All work shown in the patents was developed and reduced to practice on or before that date.

21. The Patents-in-Suit generally relate to methods of treating cancer using dendritic cells loaded with tumor antigens.

22. Claim 1 of the '806 patent claims: "A method for inducing an immunologic response in a patient comprising: (a) obtaining monocytic dendritic cell precursors from the patient; (b) culturing the monocytic dendritic cell precursors to induce differentiation into immature dendritic cells; (c) differentiating the immature dendritic cells into mature dendritic cells by (i) transfecting into the immature dendritic cells a nucleic acid composition encoding one or more tumor antigens; and (ii) contacting the immature dendritic cells with a tumor antigen composition, wherein a tumor antigen of the tumor antigen composition comprises an epitope having a sequence that overlaps minimum of 5 amino acids with the sequence of an epitope of a tumor antigen encoded by the nucleic acid composition of step (i) but is not identical thereto; (d) culturing the immature dendritic cells to produce mature dendritic cells; and (e) administering the mature dendritic cells to the patient."

23. Claim 1 of the '248 patent claims: "A method for inducing an immunologic response to a tumor in a patient comprising: (a) obtaining monocytic dendritic cell precursors from the patient, wherein the patient has breast cancer, a glioma, melanoma, pancreatic cancer or prostate cancer; (b) culturing the monocytic dendritic cell precursors to induce differentiation into immature dendritic cells; (c) differentiating the immature dendritic cells into mature dendritic cells by providing to said cells a tumor antigen composition comprising at least one Major Histocompatibility Complex (MHC) Class I epitope and at least one MHC Class II epitope, wherein the Class I and the Class II epitopes have a sequence overlap of at least 5 amino acids; (d) administering the mature dendritic cells to the patient."

24. Generally speaking, the patented method involves creating a personalized cellular "vaccine" by removing a cancerous tumor from a patient, treating cells derived from the tumor, maturing the treated dendritic cells, and reintroducing the mature dendritic cells back into the patient to fight the patient's cancer.

#### **Gensetix Obtains License to the Cancer Treatment Patents**

25. In September 2008, UT granted Mr. Alex Mirrow an exclusive license to commercialize certain work Decker and others performed while Decker was at UT. The license covers the Patents-in-Suit and any related patents and patent applications ("UT Licensed Technology").

26. UT owns the Patents-in-Suit because the patents' named inventors, including Decker, each assigned their rights to UT.

27. In January 2014, Mr. Alex Mirrow assigned his rights to Gensetix, including as to the Patents-in-Suit and any related patents and patent applications.

28. In June 2014, UT confirmed the fact of the exclusive license to Gensetix, and signed an amendment to the exclusive license.

29. Gensetix is the sole and exclusive licensee of the Patents-in-Suit and any related patents and patent applications.

30. Gensetix paid and continues to pay fees and costs in connection with the acquisition of the Patents-in-Suit.

**Decker Leaves UT But Continues Using Patented Technology**

31. Decker left UT in approximately 2011, after he completed his inventive work reflected in the Patents-in-Suit, to join the faculty at BCM.

32. On information and belief, Decker and his lab are supported by BCM.

33. Neither Decker nor BCM has ever licensed the Patents-in-Suit from UT or Gensetix. Accordingly, neither BCM nor Decker maintain any legal right to practice the methods the Patents-in-Suit claim.

34. Nonetheless, Decker continued and continues to use technology that infringes one or more claims of the Patents-in-Suit, including at least claim 1 of each of the Patents-in-Suit, as part of his work at BCM.

35. In 2013 and 2014, Decker published content while at BCM that gives Gensetix reason to believe that Decker has “used” the UT Licensed Technology, and in particular, the methods claimed in the Patents-in-Suit.

36. In 2013, Decker published an abstract in *Neuro-Oncology* entitled “Autologous Dendritic Cell Vaccine to Combat Brain Tumors in Dogs and Mice.” (“2013 Abstract”). The 2013 Abstract describes a study of “the feasibility and efficacy of dendritic cell (DC) immunotherapy against canine glioma in an effort to administer therapy” and concludes that “immunotherapy based on immunization with tumor antigen (Ag)-loaded dendritic cells (DCs) as Ag-presenting cells represents a promising strategy in the multimodal treatment for different cancers, including gliomas.”

37. The 2013 Abstract shows that Decker infringes at least claim 1 of each of the Patents-in-Suit. The 2013 Abstract reflects that its authors obtained monocytic dendritic cell precursors from canine patients, that those precursors were “differentiated into mature DCs (mDCs) using canine cytokines” using the site-specific genetic manipulation technique claimed in the Patents-in-Suit (i.e., creating a cellular “vaccine”), and that the mDCs were administered to the canine patients.

38. In 2014, Decker published an abstract in *Neuro-Oncology* entitled “Autologous Dendritic Cell Vaccine to Combat Brain Tumors in Mice and Canines.” (“2014 Abstract”).

39. Just like the 2013 Abstract, the 2014 Abstract shows that Decker infringes at least claim 1 of each of the Patents-in-Suit. The 2014 Abstract describes a study of “the feasibility and efficacy of DC immunotherapy against canine glioma in 2” canine patients and concludes that “immunotherapy, based on immunization with tumor antigen (Ag)-loaded dendritic cells (DCs) as AG-presenting cells represents a promising strategy to treat cancers.” The 2014 Abstract describes a method substantially similar to the method the 2013 Abstract describes, and which is covered by at least one claim of each of the Patents-in-Suit.

**In 2014, Gensetix Seeks Rights to the IP Decker and BCM Develop Based on the UT Licensed Technology**

40. At least as early as March 2014, Gensetix informed Decker that all information regarding Gensetix negotiations or other internal business was confidential, and that “violation of that confidentiality could damage or delay matters and subsequently the company’s bottom line.”

41. In the summer of 2014, Gensetix sought to acquire from BCM the IP rights for any technology that Decker might invent while at BCM, including that based on the UT-Licensed Technology.

42. In fact, in May of 2014, when Decker and BCM were considering filing a provisional patent application based on the UT-Licensed Technology, BCM asked Gensetix if it would “be supporting the cost for filing this provisional patent,” and Gensetix responded “Yes of course with the intent that we will be able to license it from Baylor. How do we move that forward please?” BCM then responded “Agreed. ... [Gensetix] and I will work on a license agreement to allow the company to take the lead going forward.”

43. BCM hired a patent attorney to evaluate Decker’s technology, and copied both BCM and Gensetix on communications regarding any potential Decker patents.

44. Gensetix paid BCM’s patent attorney for his work in reviewing the patentability of Decker’s additional work at BCM.

45. BCM then asked for a confidential disclosure agreement with Gensetix so that Gensetix could provide its Exclusive License Agreement with UT to BCM as a pattern for a Gensetix-BCM license agreement. Both BCM and Gensetix signed the confidential disclosure agreement, and Gensetix sent its Exclusive License Agreement to BCM.

46. BCM offered to license to Gensetix any patent applications that Decker or BCM may submit for cancer treatments based on the UT-Licensed Technology.

47. BCM and Gensetix appeared to be close to an agreement, with BCM’s attorney stating that “I don’t think it will be hard to come to resolve these issues” that Gensetix had raised with respect to BCM’s draft license agreement.

**Decker Thwarts Gensetix’s Deals with BCM and Fannin Innovation,  
and Pushes Gensetix to Work with Diakonoss**

48. In January 2015, Gensetix began meetings and negotiations with a potential business partner, Fannin Innovation (also known as Fannin Partners, LLC), to assist with funding and managing commercialization and clinical trial activities contemplated in Gensetix’s



Exclusive License Agreement with UT. Fannin Innovation expressed great interest in supporting the technology for which Gensetix held an exclusive license.

49. As Gensetix was negotiating with Fannin Innovation, Decker began requesting that Gensetix take a potential funding offer from Dan Faust of Diakonos.

50. In March 2015, while Gensetix was still negotiating with Fannin Innovation, BCM sent to Gensetix a revised “proposed BCM-Gensetix license agreement” for Gensetix’s review, and stated that “if this agreement is acceptable as-is,” BCM “can have it executed in short order.”

51. On information and belief, while Gensetix and BCM were in discussions and exchanging draft agreements, Decker independently approached BCM and, without authority or permission, made statements that disparaged Gensetix and/or discouraged BCM from concluding their agreements with Gensetix, and encouraged BCM to assign Decker’s IP to Dan Faust of Diakonos instead of to Gensetix.

52. On information and belief, Decker’s disparaging statements to BCM included many false allegations, including assertions that Gensetix would not be able to commercialize the IP, at least in part because “MD Anderson is pulling [Gensetix’s] license” to the UT-Licensed Technology. On information and belief, interfering with Gensetix’s business relationship with BCW was Decker’s primary purpose in discouraging BCM from concluding its agreement with Gensetix.

53. BCM then informed Gensetix that another party was interested in licensing any potential new Decker IP. On information and belief, this other party was Dan Faust of Diakonos.

54. Meanwhile, in April 2015, after extensive discussions and meetings between Fannin Innovation and Gensetix, Fannin Innovation sent potential partnership terms in writing to

Gensetix. Gensetix was encouraged based on the proposed terms that there was a reasonable probability that it would enter into a business relationship (a partnership that would at least include shared costs, shared equity, and management services) with Fannin Innovation.

55. Gensetix would have profited from the Fannin Innovation agreement.

56. Gensetix and Fannin Innovation never closed their expected deal, however, because Decker—acting with a conscious desire to prevent the Gensetix / Fannin Innovation deal from occurring—interfered with the potential deal. On information and belief, Decker refused to cooperate and assist Gensetix in closing the Fannin Innovation deal, because Decker insisted on working with Dan Faust of Diakonos.

57. Unbeknownst to Gensetix, Decker was secretly negotiating with Diakonos for his own deal for the benefit of himself and Diakonos rather than Gensetix. Decker's refusal to cooperate and interference with the prospective Fannin Innovation relationship caused Fannin Innovation to walk away from the relationship with Gensetix. Specifically, Fannin Innovation was unwilling to invest its time and capital because such a venture was too risky without the cooperation of Decker—the inventor of the very technology in which Fannin Innovation desired to invest.

58. Decker's interference in the prospective business relationship between Gensetix and Fannin Innovation was independently wrongful. In particular, Decker refused to cooperate with Gensetix's efforts to close the Fannin Innovation deal while also tortiously interfering with Gensetix's performance of certain commercialization and clinical trial progress obligations under the existing Exclusive License Agreement between Gensetix and UT.

59. Decker's interference in the prospective business relationship between Gensetix and Fannin Innovation was also independently wrongful because that interference reneged on a

promise he had made to Gensetix to assist with commercialization activities for the benefit of Gensetix based on the substantial funding Gensetix had provided to Decker.

60. Decker's interference with the Fannin Innovation relationship caused Gensetix injury and damages by undermining and delaying Gensetix's ability to share costs, fund, and manage commercialization activities and clinical trials. Decker's interference also caused Gensetix to spend additional time and money searching for other potential business partners once the Fannin Innovation deal did not go forward.

61. In May 2015, Gensetix reached out to Decker regarding its attempts to obtain a commercial development partner. At this time, Gensetix explained the importance of the intellectual property and patents that were developed while Decker was at UT and exclusively licensed to Gensetix. Gensetix was unaware of any relationship between Decker and Diakonos, or between BCM and Diakonos.

62. In response, on May 18, 2015, Decker confirmed the value of the Gensetix intellectual property and described it as an "impenetrable wall." Decker continues to use the Gensetix intellectual property because, in his own words, he admitted that any work that could bypass the patents "if they can exist at all, are yet to be developed."

63. Decker promised to Gensetix that he would continue to work on a cure for pediatric brain cancer – a mutual goal of Decker and Gensetix, and even asked Gensetix for additional separate funding earmarked for his lab, payable directly to him.

64. Specifically, in at least May of 2015, Decker sent emails asking Gensetix for funding for his lab, and threatened to "disengage from Gensetix" and "terminate my employees" if Gensetix did not provide the funding, but promised to cooperate with Gensetix with a "full

speed ahead mentality” to get the IND “off clinical hold” and “refrain[] from any activities that might not be in [Gensetix’s] best interests” if Gensetix provided the requested funding.

65. Gensetix “made a handshake agreement” to pay Decker to cooperate with Gensetix “to achieve the best licensing outcome for our intellectual property,” which Decker confirmed via email. Decker later asked for further confirmation of this agreement in writing, and Gensetix provided this confirmation.

66. Gensetix agreed to pay Decker fees to help develop the patented technology so it could be commercialized, and in fact paid Decker hundreds of thousands of dollars which Decker said he required to continue lab operations even while he was at BCM.

67. Gensetix then paid Decker as requested, but Decker broke his promise to cooperate with Gensetix.

68. On June 1, 2015, after conversations and meetings with Decker, BCM informed Gensetix that it was no longer interested in concluding the IP assignment agreements.

69. Decker’s interference in the prospective business relationship between Gensetix and BCM was independently wrongful. In particular, Decker refused to cooperate with Gensetix’s efforts to close the BCM assignment while also tortiously interfering with Gensetix’s performance of certain commercialization and clinical trial progress obligations under the existing Exclusive License Agreement between Gensetix and UT.

70. Decker’s interference in the prospective business relationship between Gensetix and BCM was also independently wrongful because that interference reneged on a promise he had made to Gensetix to assist with commercialization activities for the benefit of Gensetix based on the substantial funding Gensetix had provided to Decker.

71. Decker's interference with the BCM relationship caused Gensetix injury and damages by depriving it of intellectual property licenses and related revenue.

72. Instead of licensing Decker's work to Gensetix, on information and belief, BCM later assigned rights for any patent applications that BCM may submit related to Decker's work at BCM, including that related to the UT-Licensed Technology, to Diakonoss.

73. In August of 2015, Dan Faust of Diakonoss presented Gensetix with an offer that included acquiring from Gensetix the UT-Licensed Technology.

74. Gensetix turned down Diakonoss's offer.

75. When Gensetix did not agree to the terms Diakonoss proposed, on information and belief, Decker encouraged Diakonoss to proceed with its plans to at least "mov[e] forward with animal trials" without acquiring a license to the UT-Licensed Technology, with the specific intent to encourage Diakonoss to infringe the Patents-in-Suit.

76. On information and belief, Diakonoss has proceeded with at least its planned animal trials without acquiring a license to the UT-Licensed Technology.

77. Gensetix has invested time and money in applying for and obtaining patents, legal fees for intellectual property analysis, and financial support directly to Decker and his lab. In return, Decker proceeded to divert Gensetix business opportunities—such as opportunities for commercializing the UT-Licensed Technology and follow-on Decker IP—to others, including Diakonoss.

78. As a result, others, including Diakonoss, have received an unwarranted head start towards commercialization in a nascent and likely lucrative field, while Gensetix is unable to enjoy the fruits of its investments.

**By 2016, Decker and BCM Wrongfully Develop Additional Intellectual Property Based on the UT-Licensed Technology**

79. In May 2016, BCM filed two patent applications, listing Decker as an inventor: International Patent Publication Number WO 2016/179001, entitled “Methods for Enhancing an Immune Response with a CTLA-4 Antagonist” (“the ’001 application”) and International Patent Publication Number WO 2016/179475 (“the ’475 application”), entitled “Dendritic Cell Immunotherapy.”

80. On information and belief, UT provided Decker with a copy of the existing Gensetix Exclusive License Agreement, and Decker reviewed it and was aware that UT’s license to Gensetix gave it rights in “any divisional, renewal, continuation in whole or in part, substitution, conversion, reexamination, reissue, prolongation or extension thereof”—the same rights that Decker had assigned to UT in the ’806 patent.

81. On information and belief, Decker knew that any products commercializing an extension of the Patents-in-Suit could only be made or sold by infringing the UT-Licensed Technology.

82. Decker and BCM have acknowledged that the UT-Licensed Technology is “background IP” for new intellectual property that Decker developed at BCM.

83. On information and belief, Decker’s work at BCM, including at least the ’001 and ’475 applications, constitute extensions of the ’806 patent.

84. Both applications incorporate and rely upon the ’806 patent.

85. For example, the ’001 application incorporates the ’806 patent by reference in the section entitled “Dendritic Cell Populations of the Embodiments,” and cites the ’806 patent for the following proposition: “U.S. Patent 8,728,806, which is incorporated herein by reference in

its entirety, provides detailed methods for providing antigen primed dendritic cells that may be used in the compositions and methods of the embodiments.”

86. The ’475 application also incorporates the ’806 patent by reference in the sections entitled “The Present Embodiments,” and “Dendritic Cell Populations of the Embodiments,” and cites the ’806 patent for the following propositions:

- a. “Previous studies have demonstrated that dendritic cells can be effectively primed to stimulate a T-cell response that is specifically targeted to a cell population in [a] subject, such as [a] cancer cell (see, e.g., U.S. Patent 8,728,806, which is incorporated herein by reference)”;
- b. “U.S. Patent 8,728,806, which is incorporated herein by reference in its entirety, provides detailed methods for providing antigen primed dendritic cells that may be used in the compositions and methods of the embodiments”; and
- c. “In preferred aspects, primed dendritic cells for use according to the embodiments are homologously-loaded with antigen as detailed herein and in U.S. Patent 8,728,806.”

87. The ’475 application shows that Decker continues to perform the steps claimed in at least claim 1 of each of the Patents-in-Suit. It describes the use of site-specific genetic manipulation of canine patients who were diagnosed with a CNS malignancy:

- a. “Upon diagnosis of a CNS malignancy, two large (> 25 kg) canine patients were recruited for a non-randomized phase I veterinary trial. ... The first animal ... exhibited a reduction in tumor volume of 50% after a single vaccine injection (see C & D) whereas the second animal ...

exhibited a reduction in tumor volume of 79% (see G & H) after three vaccine injections.”

- b. “The following examples are included to demonstrate preferred embodiments of the invention. ... Spontaneous Canine Oligodendroglioma Treatment Model – Upon diagnosis of CNS malignancy by clinical MR imaging, large (. 25 kg) canine patients were enrolled in a non-randomized phase I trial following informed consent of the owners under an IACUC protocol established through the Translational Genomics Research Institute. Canine patients underwent craniotomy and conservative tumor resection after which the excised tumor was flash frozen in liquid nitrogen. To prepare vaccine antigens, the thawed tumor specimen was sub-divided into soluble lysate and mRNA components, and antigenic fractions were prepared as described above. ... [P]eripheral blood mononuclear cells (PBMC) were harvested. Canine DCs [dendritic cells] were generated from the adherent monocytic fraction ... Following loading with tumor antigens as described above, loaded DC matured using the same culture medium as described ... DC were then harvested ... for bilateral injection into the vicinity of the deep cervical lymph nodes by means of ultrasound sonography.”
- c. “[T]he inventors tested this approach on spontaneous brain tumors in a large animal system to demonstrate the feasibility and safety of this approach in a clinical veterinary setting. In brief, upon diagnosis of CNS malignancy by MRI, two large (> 25 kg) canine veterinary patients were



recruited following informed consent of the owners. ... [P]eripheral blood mononuclear cells (PMBC) were harvested. The adherent monocytic fraction was differentiated into DC which were simultaneously loaded with tumor lysate and mRNA subfractions and matured. DC were then harvested and resuspended in PBS for injection into the vicinity of the deep cervical lymph nodes by means of ultrasound sonography. ... The first animal received a single dose of  $5 \times 10^5$  vaccine cells and exhibited 50% tumor regression at one-month follow-up (FIGS. 7A-D). The second animal received  $5 \times 10^6$  vaccine cells over the course of three administrations and exhibited nearly 80% tumor regression (FIGS. 7E-H) at one-month follow-up. Median survival of 200 days nearly was three times greater than that (69 days) of comparable historic controls (Rossmeisl et al., 2013)."

88. A glioma, as claimed in the '248 patent, is a type of CNS malignancy.

**Decker, BCM, and Diakonos Continue to Willfully Infringe the Patents-in-Suit with Commercial Goals**

89. BCM is a business. In 2012, BCM was reported to have opened "a \$375 million cancer hospital and outpatient center." The same article explained that "Baylor and [another university] are pouring money into their facilities in an effort to attract new patients."

90. On information and belief, both BCM and Decker knew at all relevant times that using the Decker IP that BCM assigned to Diakonos would infringe the UT-Licensed Technology, including the Patents-in-Suit.

91. The work Decker is pursuing at BCM is to further BCM's business objectives, including the marketing of its faculty and staff, purportedly increasing the status of the

institution, and to lure lucrative research grants. The patent infringement at issue is therefore for a commercial purpose and commercial in nature.

92. On information and belief, Decker is developing a product to make available commercially.

93. Decker's current conduct at BCM is directed to infringing clinical trials and commercial product development. This is evidenced, for example, by Decker's application for grants directed to commercializing infringing treatments based on Decker's current conduct.

94. BCM's website quotes Decker as stating, "[t]he treatment uses the patient's own blood cells and own tumor cells to generate a powerful vaccine that can attack the tumor while sparing normal tissue. Funding of this project will enable his research group to generate the necessary data to allow a clinical trial to proceed," Decker noted."

([www.bcm.edu/news/grants/grants-support-immunotherapy-for-kids-cancer](http://www.bcm.edu/news/grants/grants-support-immunotherapy-for-kids-cancer)).

95. Decker received a grant from "Alex's Lemonade Stand Foundation," whose grants are directed to "overcome barriers that impede the translation of innovative pediatric oncology research ideas from the lab to the clinic."

96. Decker is also co-Principal Investigator "of an IND filed for intent to treat pediatric brain malignancies and will serve as co-Principal Investigator on upcoming IND filings." (<http://www.dcimmunotherapy.com/key-management>).

97. Decker's more recent publications confirm that his work, which infringes the Patents-in-Suit, is commercial in nature.

98. For example, in May 2016, Decker published an article entitled "Dendritic Cell-Secreted Cytotoxic T-Lymphocyte-Associated Protein-4 Regulates the T-cell Response by

Downmodulating Bystander Surface B7,” (“2016 Publication”), which further characterized the action of a drug already on the market—ipilimumab:

- a. “Cytotoxic T-lymphocyte-associated protein-4 (CTLA-4), the target of the blockbuster cancer immunotherapeutic ipilimumab, is one of the most well-known and well-studied members of the B7 superfamily and negatively regulates T cell responses by a variety of known mechanisms.”
- b. “Ipilimumab (anti-CTLA-4) has been administered as an anticancer therapy on the theory that its mechanism of action relies primarily upon activation of preexisting antitumor T cells by inhibition of the regulatory T-cell response or blockade of negative regulatory signaling in conventional effector T cells [46, 47]. More recent data suggest that ipilimumab might also deplete the regulatory T-cell subset in an Fc-dependent manner through ADCC [47,48]. The present study suggests that ipilimumab might provide additional anticancer efficacy through a fourth mechanism of action if administered in conjunction with immune adjuvantation and antigen-specific vaccination.”
- c. “The data indicate that blockade of DC-secreted CTLA-4 during active immune priming might enhance CD8+ T-cell responses and lead to better outcomes.”

99. Decker’s 2016 Publication provides evidence that, while at BCM, Decker has performed at least the steps of the ’806 patent through at least the following disclosure:

- a. “In vivo B16 tumor/vaccination. Mouse bone-marrow derived DC (BMDC) were prepared as follows: BM was isolated from C57Bl/6 mouse

femurs and tibias ... and immature DC were harvested on day 6. Immature BMDC were electroporated with siRNA 72h before injection and loaded and matured 24h before footpad injection into recipient mice. Recipient mice received 50,000 B16 cells subcutaneously on the flank 72h before ipsilateral DC injection. ... Tumors were measured by caliper every other day.”

100. BCM is aware of the nature of Decker’s work. Before Decker released the 2016 Publication, BCM issued a press release in April 2016 entitled “Discovery of CTLA-4 in dendritic cells opens new possibilities to fight cancer” (“Press Release”). (<https://www.bcm.edu/news/cell-and-gene-therapy/discovery-new-possibilities-to-fight-cancer>).

101. Like the 2016 Publication, the Press Release shows that Decker’s work is further characterizing the action of a drug already on the market—ipilimumab:

- a. “Ipilimumab is a Food and Drug administration-approved drug to treat melanoma. Scientists think that ipilimumab helps the body fight cancer cells by removing the ‘brake’ cancer cells place on the T cells. Ipilimumab binds to CTLA-4 on T cells, blocking signals that turn off the T cells. As a result, scientists think, T cells resume their fight against the cancer.”
- b. “These results have encouraged the Baylor researchers to suggest that strategies that combine taking away CTLA-4, or blocking it with ipilimumab, with specific tumor vaccines, of which many already exist in experimental settings, may result in better immune responses that can control tumor growth.”

102. This Press Release provides evidence that, while at BCM, Decker has performed at least the steps of the '806 patent through at least the following disclosure:

- a. “[W]e showed that dendritic cell CTLA-4 performs a very critical regulatory function. Its presence inhibits the generation of downstream anticancer responses, whereas its absence permits robust priming of such responses. These new data provide a strong rationale to use the drug ipilimumab in new and better ways, for instance in conjunction with cancer vaccines,’ said Dr. William K. Decker, assistant professor of pathology & immunology at Baylor ... and senior author of this paper. ... ‘To show the relevance of turning off the dendritic cells in the body’s response against tumors, we studied a mouse model of melanoma ... One group of mice received melanoma cells and a vaccine against the tumor made with normal dendritic cells. A second group of mice received melanoma cells and a vaccine made with dendritic cells that produce little amounts of CTLA-4. ... [T]he mice treated with dendritic cells that produce little CTLA-4 were able to develop an immune response that markedly limited tumor growth. ... These results have encouraged the Baylor researchers to suggest that strategies that combine taking away CTLA-4, or blocking it with ipilimumab, with specific tumor vaccines, of which many already exist in experimental settings, may result in better immune responses that can control tumor growth. ... Decker and Halpert own shares of Diakonon Research, Ltd.”

103. Similarly, also in 2016, Decker published an abstract for the Sarcoma Foundation of America Grants entitled “Outbred Canine Model of Adjuvant Immunotherapy for Angiosarcoma.” (“2016 Abstract”).

104. This 2016 Abstract provides further evidence that Decker’s research at BCM has involved performing the steps claimed in at least claim 1 of the ’806 patent.

105. According to the abstract, Decker and his team “propose[d] to perform a small-scale veterinary trial of adjuvant immunotherapy for canine splenic hemangiosarcoma so as to test the hypothesis that efficacy of adjuvant immunotherapy in a spontaneous canine model of splenic hemangiosarcoma ... By means of this approach, we will ... characterize the ability of the treatment regimen to provide genuine palliation or cure in canine populations.”

106. The abstract acknowledges that the described “immunotherapeutic regimen is based upon novel, patented immunology that enhances the ability of antigen presenting cells to induce a robust Th-1 polarization, generating highly cytotoxic, curative T-cell responses in vivo.”

107. Decker has described the Patents-in-Suit broadly as covering “all genuine TH1 immune responses.”

108. In 2017, Decker published an abstract in *J. Clin. Oncol.* entitled “Active specific immunotherapy for lethal canine hemangiosarcoma: A model system for the treatment of angiosarcoma with curative intent,” (“2017 Abstract”) and confirmed that he had performed the “patented immunology” regimen on canine patients as set forth in the 2016 Abstract, through at least the following disclosure:

- a. “Angiosarcoma is a deadly malignant neoplasm of the vascular endothelium. ... Though it comprises only 1% [of] all soft tissue sarcoma

diagnoses, it is a major killer among companion canines, responsible for an estimated 120,000 deaths per year in the US. ... Here we report an analysis of a phase I multi-site, open-label veterinary trial of chemo-immunotherapy performed on consecutively-presenting splenectomized companion canines with histopathologically-verified HAS. Methods: Subjects were administered two cycles of 20 mg/m<sup>2</sup> (low-dose) doxorubicin[] and an autologous cell-therapy reported to generate durable CD8<sup>+</sup> memory similar to that of physiologic viral infection. Vaccine was generated from mobilized peripheral blood and cryopreserved tumor antigen and was administered with type I interferon. ... Administration of autologous cell therapy with low-dose doxorubicin is feasible, safe, and highly efficacious in the companion canines.”

109. Upon information and belief, Diakonoss attempts to commercialize a product are connected with the work Decker is performing at BCM.

110. On information and belief, Decker owns shares in Diakonoss.

111. Diakonoss, on its website, claims it will be “offered the first right of refusal for all technologies disclosed to Baylor OTC.” But Gensetix has the enabling intellectual property for those technologies, and as a result, Diakonoss’s claims put a cloud on Gensetix’s rights to the technologies disclosed to Baylor.

112. Diakonoss, on its website, also claims it will undertake further commercial activities including “clinical data management, U.S. Food and Drug Administration (FDA) regulatory filings, management salaries, phase I manufacturing activities, and for general

corporate expenses.” It further states it is “deriving revenue from partners in the veterinary space” using the infringing technology.

113. Diakonos, on its website, further asserts that it has already undertaken phase I FDA activities, specifically “to determine the safety and feasibility of the technology in relapsed high-grade pediatric brain malignancy.”

114. Diakonos, on its website, also concedes that the company’s entire work with Decker and BCM is based on “developing the clinical version of a dendritic cell based therapy that is the ‘next generation of immunotherapy.’”

115. Diakonos, on its website, asserts that “[c]ancer immunotherapy isn’t just our core business, it’s our only business.”

116. Diakonos’s website provides evidence that Diakonos, in addition to Decker and BCM, has also infringed at least one claim of each of the Patents-in-Suit in the context of an animal drug involving site-specific genetic manipulation techniques, through at least the following disclosures:

- a. Decker is a member of Diakonos’s “Key Management,” the “co-developer of Diakonos core technologies,” and “an Assistant Professor in the Department of Pathology & Immunology at Baylor College of Medicine.” (<http://www.dcimmunotherapy.com/key-management>).
- b. Under its “publications,” Diakonos lists at least 8 of Decker’s publications dated before Decker left MD Anderson/UT in 2011. (<http://www.dcimmunotherapy.com/publications>).



- c. Under its “abstracts,” Diakonos lists at least 14 of Decker’s abstracts presented before Decker left MD Anderson/UT in 2011.  
  
(<http://www.dcimmunotherapy.com/publications>).
- d. Under its “abstracts,” Diakonos also lists the presentation version of the 2013 Abstract described above, as well as the 2014 Abstract described above.
- e. “The Diakonos core technologies work at the level of the dendritic cell (DC) to generate an anti-cancer immune response. ... Years of basic scientific research have allowed Diakonos to identify critical DC signals needed for proper immune system education and activation” such that “[t]he treatment is personalized (e.g. uses the patient’s own tumor sample and own immune system), and like any successful vaccine, is designed to be long-lasting and dramatically reduce the risk of future relapse.”  
  
(<http://www.dcimmunotherapy.com/core-technologies>).
- f. “Diakonos scientists have been focused on the reasons why dendritic cell immunotherapy has not worked, paying particular attention to ... stimulation of a certain critical immune cell subset – the plasmacytoid dendritic cell. ... Stimulation of the immune system in this fashion produces a response robust and specific enough to control physiologic cancers in large animal models. ... Patent applications covering critical elements of the treatment protocol have been filed in conjunction with Baylor College of Medicine.” (<http://www.dcimmunotherapy.com/>).

- g. Diakonos's website touts the Press Release described above.  
(<http://www.dciimmunotherapy.com/news>).
- h. Under "Clinical Updates," Diakonos first lists the "Canine Hemangiosarcoma (HSA) Trial," disclosed in Decker's 2016 Abstract and 2017 Abstract, and states: "Sarcoma, particularly splenic hemangiosarcoma, is also a devastating and lethal disease among the domestic canine population, accounting for up to 2% of all canine tumors and 1% of all deaths in dogs over the age of ten." Diakonos goes on to show graphics of the success of treatment with "Splnectomy + DC Vaccine + Low Doxorubicin," as well as a "series of canine abdominal ultrasounds" that "shows patient X's tumor ... continually shrink, scar, and ultimately resolve."

117. Gensetix and UT—not any other person or entity— should be the one reaping the benefits for the investments made in the technologies over the course of several years. Those benefits relate to commercialization of the UT-Licensed Technology, and Gensetix has the rights to such products.

118. As a result of Decker's, Diakonos's and BCM's conduct, Gensetix is and will be irreparably harmed.

**Decker, Diakonos, And BCM Interfere with Gensetix's Contract with UT**

119. Gensetix provided BCM with a copy of its existing Exclusive License Agreement contract with UT, pursuant to a Non-Disclosure and Confidentiality Agreement entered into by Gensetix and BCM. BCM reviewed and was aware of the terms of the Gensetix Exclusive License Agreement no later than July 30, 2014.

120. BCM willfully, intentionally, and improperly interfered with Gensetix's performance of certain commercialization and clinical trial progress obligations under the Exclusive License Agreement contract between Gensetix and UT by delaying Gensetix's performance of those obligations, and causing Gensetix's performance to be more expensive, burdensome, and difficult.

121. BCM willfully and intentionally interfered with Gensetix's existing contract with UT by at least the following acts:

- a. Refusing to grant Gensetix licenses to Decker patent applications and patents that Decker had previously agreed by contract were assigned to UT, and for which Gensetix owned the exclusive licenses, even though BCM knew that Gensetix had funded Decker's work at BCM.
- b. Granting licenses to Decker patent applications and patents to Diakonoss, even though BCM knew that Decker had already assigned those rights to UT, and even though BCM knew Gensetix held an exclusive license to such patent applications and patents; and even though BCM knew that Gensetix had funded Decker's work at BCM.
- c. Willfully infringing the Patents-in-Suit without a license from Gensetix, to prevent, delay, and make more expensive, burdensome, and difficult Gensetix's performance of its existing contract with UT.

122. On information and belief, Decker, BCM, and Diakonoss communicated about and agreed to the above-listed acts.

123. On information and belief, BCM performed the above-listed acts with the knowledge that these acts would make more expensive, burdensome, and difficult Gensetix's

performance of its existing contract with UT. Specifically, on information and belief, as a research university frequently engaged in licensing, BCM knew that it would be much more expensive, burdensome, and difficult for Gensetix to meet certain commercialization and clinical trial progress obligations under its Exclusive License Agreement with UT—which BCM had reviewed—with a separate party both infringing on the Patents-in-Suit and also claiming to have the rights to follow-on technology including the patents having later expiration dates than the Patents-in-Suit.

124. BCM’s actions have in fact made Gensetix’s attempts at commercializing the UT-Licensed Technology much more expensive, burdensome, and difficult. Specifically, BCM’s actions have caused Gensetix to have to expend significant time and money to find additional funding and commercialization partners other than Fannin Innovation, and have also significantly decreased the value of any deal that Gensetix can offer potential funding and commercialization partners.

125. On information and belief, UT provided Decker with a copy of the existing Gensetix Exclusive License Agreement, and Decker reviewed it and was aware of its terms.

126. Decker knew of the importance of the rights to follow-on technology, including the patents having later expiration dates than the Patents-in-Suit, to Gensetix’s performance of certain commercialization and clinical trial progress obligations under the Exclusive License Agreement between Gensetix and UT.

127. In fact, in discussing Diakonos’s negotiations with Gensetix for the rights to Gensetix’s UT-Licensed Technology, Decker stated that “Dan [Faust of Diakonos] points out some real issues that any potential biotech investor should be aware of. Given that the clinical

development timeline stands at 10-15 years, it is a valid concern that the patent has issued yet no clinical work has commenced. This patent expires in mid-2031.”

128. Decker willfully, intentionally, and improperly interfered with Gensetix’s performance of certain commercialization and clinical trial progress obligations under the Exclusive License Agreement between Gensetix and UT by delaying Gensetix’s performance of those obligations, and causing Gensetix’s performance to be more expensive, burdensome, and difficult.

129. Decker willfully and intentionally interfered with Gensetix’s existing contract with UT by at least the following acts:

- a. Refusing and encouraging BCM to refuse to grant Gensetix licenses to Decker patent applications and patents that Decker had previously agreed by contract were assigned to UT, and for which Gensetix owned the exclusive licenses, even though Decker knew that Gensetix had funded Decker’s work at BCM.
- b. Bringing Diakonos, instead of Gensetix, to BCM as a commercialization partner, and encouraging BCM to grant licenses to Decker patent applications and patents to Diakonos, even though Decker knew that he had already assigned those rights to UT, and even though Decker knew Gensetix held an exclusive license to such patent applications and patents; and even though Decker knew that Gensetix had funded his work at BCM.
- c. Willfully infringing the Patents-in-Suit without a license from Gensetix, to prevent, delay, and make more expensive, burdensome, and difficult Gensetix’s performance of its existing contract with UT.

- d. Reneging on his promise to Gensetix to work on commercialization of the inventions for the benefit of Gensetix, in exchange for Gensetix's agreement to fund Decker's work at BCM.
- e. Refusing to cooperate with Gensetix's efforts to secure additional funding and investment for commercialization and clinical trial activities by refusing to cooperate and insisting to work only with Diakonos.

130. On information and belief, Decker, BCM, and Diakonos communicated about and agreed to the above-listed acts.

131. On information and belief, Decker performed the above-listed acts with the knowledge that these acts would make more expensive, burdensome, and difficult Gensetix's performance of its existing contract with UT. Specifically, on information and belief, as a company itself engaged in licensing and commercialization and "devoted to the development of dendritic cell-based cancer therapies," Diakonos knew that it would be much more expensive, burdensome, and difficult for Gensetix to meet certain commercialization and clinical trial progress obligations under its Exclusive License Agreement with UT—which Diakonos had reviewed—while Diakonos was both infringing the Patents-in-Suit and also claiming to have the rights to follow-on technology including the patents having later expiration dates than the Patents-in-Suit.

132. Additionally, although Decker committed to working with Gensetix to commercialize the UT-Licensed Technology, in exchange for Gensetix funding his lab, Decker is now working with Diakonos to commercialize this technology. On information and belief, Decker knew that his failure to honor his commitment to work with Gensetix (and switch to working with Diakonos) makes Gensetix's commercialization of the UT-Licensed Technology

(that Decker invented) under its Exclusive License Agreement more expensive, burdensome, and difficult.

133. Decker's actions have in fact made Gensetix's attempts at commercializing the UT-Licensed Technology much more expensive, burdensome, and difficult. Specifically, Decker's actions have caused Gensetix to have to expend significant time and money to find additional funding and commercialization partners other than Fannin Innovation, and have also significantly decreased the value of any deal that Gensetix can offer potential funding and commercialization partners.

134. On information and belief, Decker disclosed the existing Gensetix Exclusive License Agreement and/or its material terms to Diakonos, and Diakonos was aware of its terms.

135. Additionally, in June of 2015, Diakonos requested to see the existing Gensetix Exclusive License Agreement as part of its licensing negotiations with Gensetix. Diakonos then sent an NDA to Gensetix (after rejecting Gensetix's own NDA) and executed this NDA, in order to view the Gensetix Exclusive License Agreement. Under this NDA, Diakonos received this Exclusive License Agreement from Gensetix, and Diakonos was aware of its terms.

136. Diakonos knew of the importance of the rights to follow-on technology, including the patents having later expiration dates than the Patents-in-Suit, to Gensetix's performance of certain commercialization and clinical trial progress obligations under the Exclusive License Agreement between Gensetix and UT.

137. In fact, in negotiating with Gensetix for the rights to Gensetix's UT-Licensed Technology, Dan Faust of Diakonos stated that he viewed it as a "major concern[]" that the Patents-in-Suit had been "filed over 7 years ago," arguing that "[t]he window of opportunity gets smaller each year a patent 'cures.' The perception of 'lost opportunity' in the market place,

whether valid or not, is difficult to overcome. This has a negative impact on the value of the project.”

138. Diakonos willfully, intentionally, and improperly interfered with Gensetix’s performance of certain commercialization and clinical trial progress obligations under the Exclusive License Agreement between Gensetix and UT by delaying Gensetix’s performance of those obligations, and causing Gensetix’s performance to be more expensive, burdensome, and difficult.

139. Diakonos willfully and intentionally interfered with Gensetix’s existing contract with UT by at least the following acts:

- a. Encouraging BCM and Decker to grant Diakonos a license instead of Gensetix—and entering into a license agreement with BCM and Decker—for Decker patent applications and patents that Diakonos knew Decker had previously agreed by contract were assigned to UT, and for which Diakonos knew Gensetix owned the exclusive licenses.
- b. Publicly announcing that Diakonos had obtained rights to Decker patent applications and patents that had already been assigned to UT and exclusively licensed to Gensetix, to cloud Gensetix’s exclusive license in order to prevent, delay, and make more expensive, burdensome, and difficult Gensetix’s performance of its existing contract with UT.
- c. Willfully infringing the Patents-in-Suit without a license from Gensetix, to prevent, delay, and make more expensive, burdensome, and difficult Gensetix’s performance of its existing contract with UT.



140. On information and belief, Decker, BCM, and Diakonos communicated about and agreed to the above-listed acts.

141. On information and belief, Diakonos performed the above-listed acts with the knowledge that these acts would make more expensive, burdensome, and difficult Gensetix's performance of its existing contract with UT. Specifically, on information and belief, as a company itself engaged in licensing and commercialization and "devoted to the development of dendritic cell-based cancer therapies," Diakonos knew that it would be much more expensive, burdensome, and difficult for Gensetix to meet certain commercialization and clinical trial progress obligations under its Exclusive License Agreement with UT—which Diakonos had reviewed—while Diakonos was both infringing the Patents-in-Suit and also claiming to have the rights to follow-on technology, including patents later expiration dates than the Patents-in-Suit.

142. Diakonos's actions have in fact made Gensetix's attempts at commercializing the UT-Licensed Technology much more expensive, burdensome, and difficult. Specifically, Diakonos's actions have caused Gensetix to have to expend significant time and money to find additional funding and commercialization partners other than Fannin Innovation, and have also significantly decreased the value of any deal that Gensetix can offer potential funding and commercialization partners.

143. On information and belief, Decker, Diakonos, and BCM had an agreement amongst themselves to willfully and intentionally interfere with Gensetix's existing contract with UT.

144. Decker informed Gensetix that he had spoken with BCM regarding Diakonos's licensing of the Decker lab IP at BCM.

145. Decker also informed Gensetix that he had spoken with Dan Foust of Diakonos regarding Gensetix's UT-Licensed Technology.

146. Defendants' actions have caused and are continuing to cause injury and damages to Gensetix at least by frustrating and delaying Gensetix's ability to fund commercialization and clinical trial activities, and by making it more expensive, burdensome, and difficult for Gensetix to perform its existing contract with UT as detailed above.

**FIRST COUNT – As To Diakonos, Decker and BCM**  
**(Willful Infringement of the '806 Patent)**

147. Gensetix repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

148. Upon information and belief, Decker, Diakonos, and BCM are infringing claim 1 of the '806 patent, and discovery is expected to show they are infringing additional claims.

149. Upon information and belief, Decker, Diakonos, and BCM will commercially benefit from continuing to infringe the '806 patent. Decker, Diakonos, and BCM will use the patented method, or manufacture or sell products or therapies, including veterinary products or therapies, that use the patented method.

150. Upon information and belief, Decker, Diakonos, and BCM have been taking and will take steps to induce and/or contribute to third-party infringement of one or more claims of the '806 patent.

151. Decker, Diakonos, and BCM were aware of the '806 patent before the filing of this action, and despite such knowledge they have taken actions that have willfully infringed and continue to willfully infringe one or more claims of the '806 patent, thus rendering their infringement egregious under 35 U.S.C. § 284.

152. Gensetix is suffering irreparable harm as a result of Defendants' willful infringement. Gensetix also seeks monetary relief for past and future willful infringement.

**SECOND COUNT – As to Diakonos, Decker and BCM**  
**(Willful Infringement of the '248 Patent)**

153. Gensetix repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

154. Upon information and belief, Decker, Diakonos, and BCM are infringing claim 1 of the '248 patent, and discovery is expected to show they are infringing additional claims.

155. Upon information and belief, Decker, Diakonos, and BCM will commercially benefit from continuing to infringe the '248 patent. Decker, Diakonos, and BCM will use the patented method, or manufacture or sell products or therapies, including veterinary products or therapies, that use the patented method.

156. Upon information and belief, Decker, Diakonos, and BCM have been taking and will take steps to induce and/or contribute to third-party infringement of one or more claims of the '248 patent.

157. Decker, Diakonos, and BCM were aware of the '248 patent before the filing of this action, and despite such knowledge they have taken actions that have willfully infringed and continue to willfully infringe one or more claims of the '248 patent, thus rendering their infringement egregious under 35 U.S.C. § 284.

158. Gensetix is suffering irreparable harm as a result of Defendants' willful infringement. Gensetix also seeks monetary relief for past and future willful infringement.

**THIRD COUNT – As to Decker**  
**(Breach of Contract)**

159. Gensetix repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

160. Gensetix and Decker entered into a “Non-Disclosure and Confidentiality Agreement” effective March 19, 2015. The agreement prevented Decker from disclosing any Gensetix confidential information to third parties, specifically in view of anticipated consulting, funding and marketing of the exclusive license held by Gensetix.

161. Pursuant to that agreement, Gensetix disclosed confidential information to Decker about, among other things, Gensetix’s rights to the UT-Licensed Technology, negotiations with BCM for additional IP arising from Decker’s lab at BCM, assessments of the protectable IP arising from Decker’s technology, financials, and other information relating to financing opportunities with parties such as Fannin Innovation.

162. On information and belief, Decker disclosed to Dan Faust of Diakonos—without Gensetix’s permission—confidential information of Gensetix, including confidential information about Gensetix’s rights to the UT-Licensed Technology, negotiations with BCM for additional IP arising from Decker’s lab at BCM, assessments of the protectable IP arising from Decker’s technology, financials, offers for funding and commercialization from parties such as Fannin Innovation, and other sensitive information that belonged to Gensetix.

163. By April of 2015, on information and belief, based on Decker’s disclosures, Dan Faust of Diakonos used Decker’s disclosures of confidential Gensetix information to begin negotiating with BCM for rights to IP arising from Decker’s lab at BCM.

164. On information and belief, Dan Faust’s improper use of confidential Gensetix information during negotiations caused BCM to inform Gensetix on June 1, 2015 that it was withdrawing its offer to license to Gensetix IP arising from Decker’s lab at BCM.

165. On information and belief, on June 24, 2015—just three months after the effective date of the Gensetix-Decker confidentiality agreement—Dan Faust registered Diakonos Research Ltd. as a corporate entity.

166. Decker's misconduct has caused and continues to cause harm to Gensetix. In particular, as a result of Decker's breach, Diakonos is now developing commercial treatments for the benefit of Diakonos, Decker, and BCM instead of for the benefit of Gensetix and UT.

167. Gensetix is suffering irreparable harm as a result of Decker's breach. Gensetix has also suffered damages as a result of Decker's breach, in the form of additional out-of-pocket costs, lost intellectual property licenses, lost revenue, and lost goodwill.

**FOURTH COUNT - As to Decker**  
**(Tortious Interference –Gensetix/BCM Deal)**

168. Gensetix repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

169. Gensetix in 2014 was pursuing business deals to acquire licenses to intellectual property for any work Decker did at BCM. Gensetix had a reasonable expectation of a business relationship with BCM for acquiring this IP.

170. Decker was aware of these business dealings with BCM.

171. On information and belief, Decker willfully and intentionally interfered with Gensetix's business opportunities and deliberately acted in a way that would cause the business dealings with BCM to suffer, including by communicating with them to disparage and/or discourage BCM from concluding their agreements with Gensetix.

172. Gensetix did not reach agreement with BCM as a result.

173. Decker's interference with the prospective business relationship between Gensetix and BCM was independently wrongful as alleged herein.

174. Gensetix is suffering irreparable harm as a result of these violations. Gensetix also suffered damages as a result, in the form of additional out-of-pocket costs, lost intellectual property licenses, and lost revenue.

**FIFTH COUNT - As to Decker**  
**(Tortious Interference – Gensetix/Fannin Innovation Deal)**

175. Gensetix repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

176. Gensetix in 2015 was pursuing a business deal to sell part of its interest in the UT-Licensed Technology to Fannin Innovation. Gensetix had a reasonable expectation of a business relationship with Fannin for selling this IP.

177. Decker was aware of these business dealings with Fannin Innovation.

178. On information and belief, Decker purposefully and knowingly interfered with Gensetix's business opportunities and deliberately acted in a way that would cause the business dealings with Fannin Innovation to suffer, including by communicating with them to disparage and/or discourage Fannin Innovation from concluding its agreement with Gensetix.

179. Gensetix did not reach agreement with Fannin Innovation as a result.

180. Decker's interference with the prospective business relationship between Gensetix and Fannin Innovation was independently wrongful as alleged herein.

181. Gensetix is suffering irreparable harm as a result of these violations. Gensetix also suffered damages as a result, in the form of additional out-of-pocket costs, lost revenue, and goodwill.

**SIXTH COUNT – As to Decker**  
**(Promissory Estoppel)**

182. Gensetix repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

183. In reliance on “handshake agreement” promises made by Decker as recently as May of 2015, and confirmed by Decker via email, to develop a commercial product and “refrain[] from any activities that might not be in [Gensetix’s] best interests,” Gensetix paid large sums of money personally and directly to Decker to support his lab work.

184. Decker understood and agreed that if his cancer treatments were to become more widely available, then Gensetix would be entitled to the benefits and revenues as a result of Gensetix’s investments.

185. Decker nonetheless diverted the money and now is developing commercial treatments for the benefit, not of Gensetix, but of third parties such as Diakonos and BCM.

186. Decker’s misconduct has caused and continues to cause harm to Gensetix.

187. As a result, Gensetix has suffered damages in the form of out-of-pocket expenses Gensetix paid in reliance on Decker’s promises.

**SEVENTH COUNT – As to Decker, Diakonos, and BCM**  
**(Tortious Interference with Existing Contract)**

188. Gensetix repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

189. Gensetix had and continues to have an existing contract with UT in the form of an Exclusive License Agreement.

190. Decker, Diakonos, and BCM have willfully and intentionally interfered with Gensetix’s existing contract with UT as alleged herein.

191. Defendants’ interference with Gensetix’s existing contract has caused injury and damages to Gensetix, at least by frustrating and delaying Gensetix’s ability to fund commercialization and clinical trial activities, and by making it more expensive, burdensome, and difficult for Gensetix to perform its existing contract with UT as alleged herein.

192. Gensetix is suffering irreparable harm as a result of these violations. Gensetix also suffered damages as a result, in the form of additional out-of-pocket costs, lost revenue, and goodwill.

**EIGHTH COUNT – As to Decker, Diakonos, and BCM**  
**(Civil Conspiracy)**

193. Gensetix repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

194. On information and belief, Decker, Diakonos, and BCM had an agreement amongst themselves to willfully and intentionally interfere with Gensetix's existing contract with UT as alleged herein.

195. Decker, Diakonos, and BCM have intentionally and overtly interfered with Gensetix's existing contract with UT as alleged herein.

196. Defendants' conspiracy to interfere with Gensetix's existing contract has caused injury and damages to Gensetix, at least by frustrating and delaying Gensetix's ability to fund commercialization and clinical trial activities, and by making it more expensive, burdensome, and difficult for Gensetix to perform under its existing contract with UT as alleged herein.

197. Gensetix is suffering irreparable harm as a result of these violations. Gensetix also suffered damages as a result, in the form of additional out-of-pocket costs, lost revenue, and goodwill.

**NINTH COUNT – As to Decker, Diakonos, and BCM**  
**(Declaratory Judgment)**

198. Gensetix repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.



199. Diakonoss purports to have a “first right of refusal” to Decker’s work using the infringing technology disclosed to BCM. But Gensetix holds senior interest in the technology and in the intellectual property.

200. This count arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that Gensetix—not Diakonoss, Decker, or BCM—has the right and title to revenues derived from Decker’s work using the infringing technology.

201. There is an actual and justiciable controversy between the parties concerning patent infringement and the relative rights of Gensetix and Diakonoss, Decker, and BCM in the commercialization of the infringing technology.

202. Gensetix is entitled to a judicial declaration that any and all revenues derived from Defendants’ work using the infringing technology belong to and are due to Gensetix.

### **PRAYER FOR RELIEF**

WHEREFORE, Gensetix respectfully request that the Court enter a Judgment and Order in their favor and against Defendants as follows:

A. For a declaration and judgment that Diakonoss, Decker, and BCM have infringed, and any future use of the methods will infringe, at least claim 1 of the ’806 patent either directly or indirectly, with damages awarded to Gensetix.

B. For a declaration and judgment that Diakonoss, Decker, and BCM have infringed, and any future use of the methods will infringe, at least claim 1 of the ’248 patent either directly or indirectly, with damages awarded to Gensetix.

C. Injunctive relief precluding Defendants from manufacturing, using, selling, offering to sell, or importing items or methods that infringe the Patents-in-Suit before they expire.

D. A judgment pursuant to 35 U.S.C. § 284, finding willful patent infringement by Diakonos, Decker, and BCM, and awarding Gensetix treble damages.

E. A judgment finding that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Gensetix costs and attorneys' fees.

F. A judgment that Decker has tortiously interfered with business opportunities with BCM belonging to Gensetix, with damages awarded to Gensetix.

G. A judgment that Decker has tortiously interfered with business opportunities with Fannin belonging to Gensetix, with damages awarded to Gensetix.

H. A judgment that Decker, Diakonos, and BCM have tortiously interfered with Gensetix's existing contract with UT, with damages awarded to Gensetix.

I. A judgment that Decker, Diakonos, and BCM entered into a civil conspiracy to tortiously interfere with Gensetix's existing contract with UT, with damages awarded to Gensetix.

J. A judgment that Decker is liable for promissory estoppel, based on representations, and actions such that Gensetix is entitled to recovery, with damages awarded to Gensetix.

K. A judgment that Decker violated his duty of confidentiality and breached a confidentiality agreement, with damages awarded to Gensetix.

L. A declaration that Gensetix has the right to all revenues stemming from Decker's work at BCM using the infringing technology.

M. A judgment awarding Gensetix its costs under Fed. R. Civ. P. 54(d) and 28 U.S.C. § 1920; and

N. Such other and further relief as this Court may deem just and proper.

Date: June 23, 2017

Respectfully submitted:

/s/ Sarah E. Spires

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**CERTIFICATE OF SERVICE**

On June 23, 2017, I electronically submitted the foregoing document with the clerk of the court for the U.S. District Court, Southern District of Texas, using the electronic case filing system of the court. I hereby certify that I have served all counsel and/or pro se parties of record electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

/s/ Sarah E. Spires

Sarah E. Spires